

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 is unclear as for "and the balloon will secure the balloon in place". It is not understood what is meant by this language.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 positively recites a blood vessel, which is a body part and by reciting such includes part of a human being as part of the invention. Such is not permitted. Applicant can change the language to make it an intended use such as stating "at least one balloon adapted to be placed alongside a portion of the blood vessel" to avoid the rejections.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 5-6, 8, 11-13, 16-17, 19, 22, 25-26 are rejected under 35

U.S.C. 102(b or e) as being anticipated by Khaghani et al. USPN 6,984,201 - 102(e) or WO 02/24254 - 102(b). Referencing the US patent, Khaghani et al. teach a pressure applying device 1 comprising a balloon 10 with optionally two or more balloon compartments (column 9, lines 55-60, column 15 lines 10-11), a restrainer 11 formed as a sleeve (column 8 lines 54-63), a control console comprising an inflation unit 30, an ecg sensor 51, and a control unit 50. Khaghani et al also teaches a sheath 33 (column 12 lines 25-30 Figure 8). The at least 2 balloon compartments may be independently inflatable (column 15 lines 10-13). The control console may be implantable in a patient (column 9, lines 10-12, column 14, lines 41-42, column 16, lines 57-60) The pressure applying device 1 may be aced around an artery such as the descending aorta ( column 13, lines 59-60 Fig. 11)

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 8-11, 12-13, 19-22, 25 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chiu USPN 5,429,584 alone or alternatively in view of Pacella et al USPN 6,045,496. Chiu teaches an implantable control console and inflation unit 10 and 54, heart rate sensing means 24, bladder 10 and flow director 54, a sleeve restrainer 16 and a balloon member 52 for compressing the aorta against the sleeve. Applicant's statements of intended use such as where the controller is adapted to be worn are given little to no patentable weight since they impart no meaningful structure and the controller is capable of being worn anywhere. While the sensor of Chiu is unspecified as to the type but stated as a heart rate sensor, because it is considered to detect electrocardiograph signals such as systole and diastole it is considered to meet applicant's claim language. Applicant does not require the sensor to detect electrical signals of the heart, only those signals that are represented on an electrocardiograph. However, in the event such claims are read more narrowly, to have used an ecg detector would have been obvious in view of Pacella.

Claims 3-4, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaghani et al. USPN 6,984,201, Khaghani et al. WO 02/24254 or Chiu USPN 5,429,584 (alone or further in view of Pacella et al USPN 6,045,496) as applied above to claims 1-2, and 12-13 and further in view of Hakim USPN 3,675,656. To have provided the restrainer sleeve 16 of Chiu with a protrusion member of Hakim (element 36) for ensuring complete closure of the vessel would have been obvious. To have

made it in to an annular protrusion to accommodate movement of the blood vessel within the sleeve member would have been apparent to those of ordinary skill in the art.

Claims 7, 18, 23-24, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiu USPN 5,429,584 alone or alternatively in view of Pacella et al USPN 6,045,496. The examiner takes official notice that using blood pressure for detecting heart rate and for verifying an ecg are well known. To have included a blood pressure sensor in the Chiu heart rate sensor would have been obvious. Including a sheath attachment member to prevent the balloon member from falling out of the sleeve would have been obvious. To have used the compression member with other arteries such as the iliac to prevent back flow would have been obvious.

Claims 5-6, 16-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Chiu USPN 5,429,584 alone or alternatively in view of Pacella et al USPN 6,045,496, and further in view of Habib USPN 5,372,573.

Applicant differs in reciting multiple balloon compartments. Habib shows such an arrangement for squeezing vessels. To have included such the Chiu compressing device would have been an obvious substitution to complete the same task.

Claims 9-10, 20-21 are rejected under 35 U.S.C. 102(b or e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Khaghani et al. USPN 6,984,201 - 102(e) or WO 02/24254 - 102(b). The limitations of claims 9-10, 20-21 are read to be intended use statements and not actual structure or method steps. There is no reason that the controller of Khaghani is not capable of being attached to a belt, although prior to an implantation. Thus, the device is considered to be small enough to

be carried by the patient (inside the body) and is capable of being attached to a belt. Alternatively if the claims are read more narrowly, the substitution of an external controller carried by a belt on a person would have been an obvious alternative, known to the art.

Claims 7, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaghani et al. USPN 6,984,201 or WO 02/24254 alone or in view of in view of Wang USPN 6,454,697. Applicant differs in reciting a blood pressure sensor in addition to the ecg sensor. To have included a pressure sensor to adjust counter pulsation in the event of blood pressure that is outside of a safety range would have been an obvious inclusion. Wang is cited as an example of maintaining safe blood pressures in an ecg controlled heart assist device.

Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Khaghani et al. USPN 6,984,201 or WO 02/24254. To have merely lowered the positioning of the counterpulsation device down the ascending aorta and to the iliac arteries would have been an obvious alternative location for the device. Applicant's specification provides minimal discussion of such a location and appears to be an after thought with no stated criticality.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 8:00 - 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark W Bockelman/  
Primary Examiner, Art Unit 3766  
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